

# **ADMINISTRATIVE GUIDELINES FOR NUTRITION OBESITY RESEARCH CENTERS (NORCs)**

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**PART I**

**DESCRIPTION AND STRUCTURE OF A  
NUTRITION OBESITY RESEARCH CENTER  
(NORC)**

## **NORC Guidelines**

### **Nutrition Obesity Research Centers**

#### **A. Introduction**

The NIDDK-supported Nutrition Obesity Research Centers (NORC) program is intended to integrate, coordinate, and foster interdisciplinary basic, clinical, and public health research by a group of established investigators actively conducting programs of important, high-quality research that is related to a common nutritional sciences and/or obesity theme or themes. NORCs are also intended to improve the quality and multidisciplinary nature of research in nutritional sciences and/or obesity by providing shared access to specialized technical resources and expertise. These centers provide increased, cost effective, collaboration among multidisciplinary groups of investigators at institutions with an established, comprehensive research base in nutritional sciences and/or obesity and related areas.

The Division of Digestive Diseases and Nutrition (DDN) within NIDDK supports twelve NORCs. NORCs are not intended to support research programs that meet guidelines of other ongoing NIDDK centers programs, including the Diabetes Research Centers (DRCs) and/or the Digestive Diseases Research Centers (DDRCs).

This document provides a description of and administrative guidelines for NORCs, P30 core center grants, which will provide needed resources for basic and clinical nutritional sciences and/or obesity research.

#### **B. Description and Basic Requirements**

##### **Background**

Advances in nutritional sciences and obesity research are derived from, and dependent on, many disciplines such as biochemistry, molecular biology, (epi)genetics, and physiology and on medical specialties such as internal medicine, pediatrics, and surgery. Both nutritional sciences and obesity research are interdisciplinary and are dependent on close interactions among researchers, health services providers, and educators to achieve stated goals.

There is a great public desire for more information on nutrition and how the foods we consume affect our health. There is also a growing public desire for more information on the development, treatment, and prevention of obesity. The National Institutes of Health (NIH) has performed and supported research relating to obesity and continues to have a major commitment to developing new nutritional information and imparting this information to physicians, other health professionals and the public. The NORCs will help to combat the serious public health problem of obesity and will support research in nutritional sciences to better understand the relationship between health and nutrition.

It is appropriate for a NORC to be established to support mainly nutritional sciences research without an obesity research program, as it is appropriate for a NORC to have a concentration of research in obesity and related areas such as eating behaviors and disorders; energy metabolism and regulation; abnormalities of energy balance, such as anorexia nervosa, AIDS, and cancer; or weight management, including the role of physical activity. Likewise, a NORC may have a combination of both nutritional sciences and obesity research at their center. Therefore, throughout this document, NORCs will be discussed in terms of supported nutritional sciences and/or obesity research.

## **General Description and Basic Requirements**

The overall goal of the NORC is to bring together, on a cooperative basis, basic science and clinical investigators to enhance and extend the effectiveness of nutritional sciences and/or obesity research. The specific objectives of an NORC include efforts (1) to create or strengthen a focus in biomedical research institutions for multidisciplinary and interdisciplinary research in nutritional sciences and/or obesity; (2) to develop new knowledge concerning the etiology, development, assessment, treatment, and prevention of nutrition-related diseases, obesity, and eating disorders; (3) to understand control and modulation of energy metabolism in obesity, including the interaction between physical activity, nutrient metabolism, and food intake; (4) to understand and treat disorders associated with abnormalities of energy balance and weight management such as in anorexia nervosa, AIDS, and cancer; and (5) to strengthen training environments to improve the education of medical students, house staff, practicing physicians, and allied health personnel with regard to these conditions.

NORCs are also strongly encouraged to facilitate clinical investigations such as translation of research finds into practical treatments for patients and/or provide the opportunity for Center members to obtain clinical samples and patient data needed for their research. In addition to facilitating studies aimed at a better understanding of the natural history and etiology of diseases, such components may support biostatistics consultation; assist with clinical study design; foster collaboration among researchers; aid in recruitment of subjects for clinical studies; provide data entry support for epidemiological studies; or provide modest funding for tissue, DNA, or serum storage.

A NORC must be an identifiable organizational unit within a single university, medical center, or a consortium of cooperating institutions. NORCs will be supported using the P30 center grant mechanism, which provides support for shared resources, termed "cores," that enhance productivity and benefit a group of investigators working to accomplish the stated goals of the NORC. Thus, the purpose of the NORC is to provide the capability for accomplishments greater than those that would be possible by individual research project grant support alone.

## **Research Base**

To qualify for an NORC grant, the applicant institution **must** already have a substantial base of ongoing, independently supported, peer-reviewed research projects related to the study of nutritional sciences and/or obesity and related areas, a portion of which should be clinical and/or translational research. The research base must exist prior to the submission of an application. The research base for a core center is made up of investigators with individually-funded research projects who can benefit from shared resources. **The biomedical research base will be given emphasis in the peer review process.** Focus, relevance, interrelationships, quality, productivity, and, to some extent, quantity, are all considerations in judging the adequacy of the research base. Although collaborations with investigators outside the applicant institution/consortium are encouraged, the research base includes **ONLY** support for the investigators at the applicant institution/consortium.

The currently funded **research base** provides the major support for a group of investigators who would benefit from shared resources. The body of research described as the research base includes only currently funded, peer-reviewed research grants awarded to the applicant institution/consortium. These may be federally or privately funded awards. Peer-reviewed federally-supported research must comprise at least 50% of the identified research base.

The qualifications, experience, and commitment of the NORC **investigators** responsible for the individual research base grants and their willingness to cooperate with each other and contribute to the overall objectives of the NORC will be considered. In **renewal** applications, the degree to which effective collaborations fostered by the Center and the cores have resulted in new projects will be considered.

Institutional training grants/programs, pre/post-doctoral fellowship awards, and other P30s/CTSAs are not considered part of the research base. However, participants in the NORC program are encouraged to become fully integrated into, and synergistic with, other NIDDK- and NIH-funded Core Centers and Programs within their institutional setting. This includes the clinical research homes being established by the Clinical and Translational Science Awards supported by the National Institutes of Health (<http://www.ctsaweb.org/>) and other related NIH roadmap activities, and any related NIDDK-funded Center programs such as the Diabetes Research Centers (DRC) Program. Applicants should provide information on other programs supporting related resources at their institution and describe the nature of synergy and integration between the NORC and these other activities.

Applicants should also describe any training opportunities afforded by the NORC for Center participants, and document ways the Center would facilitate, enhance or foster the institutional training environment. Specifically, Center applicants should provide information on related NIDDK T32 training programs at the Center institution(s), and describe how the NORC will help to integrate, facilitate and enhance activities of T32-supported trainees.

Eligibility for an award is limited to domestic institutions.

### **Biomedical Research Cores**

Cores are shared facilities that serve to enhance or make more cost effective the services, techniques, or instrumentation used by the investigators within the NORC. Cores should extend, support, and contribute to the work of the Center members and should support nutrition/obesity and other related areas. Cores may be based solely at the applicant institution or at multiple institutions through subcontracts. If subcontracts are to be utilized the applicant must clearly demonstrate how a cohesive and integrated operation will be ensured and describe the advantages of this approach to the performance of core functions.

A Center should have a minimum of two cores in addition to the **Administrative Core** (described below). The Administrative Core is a required element and must be an identifiable organizational unit within an academic or university medical center or a consortium of cooperating institutions including the university-affiliated Center. Such a Center will involve the interaction of broad and diverse elements; thus, lines of authority and approval by the appropriate institutional officials must be clearly specified. The administrative core plays a key role in the coordination and functioning of the center.

### **C. Administrative Core**

#### **Description**

A NORC will involve the interaction of broad and diverse elements; thus, lines of authority and sanction by the appropriate institutional officials must be clearly specified. In the event of a consortium of institutions being involved, agreement as to how the lines of authority will be managed among the participating organizations needs to be documented. The administrative core of the NORC is responsible for maintaining these lines of authority, coordinating the various functions of the NORC, and serving as the visible contact point between the university community and the NORC. Therefore, each NORC must contain an Administrative Core.

## Requirements

### *Director*

Each NORC must name a Director who is responsible for its organization and operation. The Director is the Principal Investigator of the P30 application for a NORC and is the Director of the Administrative Core. The Director must be an experienced and respected researcher who can provide scientific and administrative leadership for the entire program. The Director must be able to coordinate, integrate, and provide guidance in establishing, expanding, or focusing programs of nutritional sciences and/or obesity research. An Associate Director should be named who will be involved in both the scientific and administrative aspects of the NORC. The Associate Director will serve as acting Director in the absence of the Director.

More than one PD/PI, or multiple PDs/Pis, may be designated for NORCs. The decision of whether to apply for a grant with a single PD/PI or multiple PDs/Pis is the responsibility of the investigators and applicant organizations, and should be determined by the scientific goals of the Center. Applications for grants with multiple PDs/Pis will require additional information in the application and the review criteria for an application with multiple PD/PI will be modified. When considering multiple PDs/Pis, please be aware that the structure and governance of the PD/PI leadership team as well as the knowledge, skills and experience of the individual PDs/Pis will be factored into the assessment of the overall scientific merit of the application. As with all multiple PD/PI applications to NIH, a contact PI must be designated. The contact PI will be responsible for communication between the NIH and the rest of the leadership team

### Administrative Core Components

Three other activities may be supported and budgeted through the Administrative Core:

1. Pilot and Feasibility (P/F) Program;
2. Enrichment Program
3. Clinical Component (Optional; See F. Clinical Component for instructions)

The **Pilot and Feasibility (P/F) Program** provides modest support for new initiatives or feasibility projects for either new investigators or for established investigators who are moving into research areas of direct interest to the NORC. These areas may include biomedical, epidemiological, clinical, or behavioral research as they pertain to the NORC goals. Pilot and feasibility projects evaluating the effectiveness of a model program for translating research in biomedical and behavioral science into routine clinical care also are encouraged.

The **Enrichment Program** provides limited funds to sponsor, for example, seminars, visiting scientists, workshops, and mini-sabbaticals for Center members. These activities are aimed at fostering the exchange of ideas with the goal of enhancing the productivity and efficiency of the NORC and its members.

### *Organization and Functions*

The administrative structure of the NORC, for the most part, will be left to the discretion of the applicant institution, as long as minimum requirements are met. The effective development of a Center requires close interaction between the Center Director, the Center investigators, institutional administrative personnel, the staff of the NIDDK, and other members of the institution in which the Center is located.

The organization of the Administrative Core provides a supportive structure for the NORC. As part of this structure, for example, an Internal Executive Committee should be named whose duties include: (1) coordinating and integrating the NORC components and activities; (2) administering the enrichment program in a productive and efficient manner; (3) reviewing the use of funds for P/F projects; (4) advising the Director as to the productivity and effectiveness of the activities of the NORC; and (5) interacting with other Centers, NIDDK, and other appropriate groups and/or individuals, including both the scientific and lay communities. It may be helpful to include a non-NORC member on the Internal Executive Committee to provide the view point of someone not using the center in setting priorities and evaluating the operations of the center.

Formation of an **External Advisory Board** to the NORC is mandatory. This Board advises the Director on budget, policy, scientific focus, core use assessments, and other issues related to the workings of the Center. A group of four to seven members selected for their scientific expertise and administrative oversight skills is recommended. For new applications, a description of the expertise of individuals to be considered for this external advisory board should be described, but it is preferred that invitations to these individuals not be extended until the NORC is actually in place. The External Advisory Board should meet at least once a year, on site, to review the NORC.

The Administrative Core oversees the P/F program. The review of P/F project applications must include the use of appropriate consultants from the scientific community outside the NORC. This may be another function of the External Advisory Board. Further details regarding the selection process for P/F projects can be found in Part I, G of these guidelines. Typically the Director designates someone to oversee the P/F program for the NORC, e.g., the Associate Director or other Center member.

The Administrative Core also assumes responsibility for the Enrichment Program. The selection process, oversight, and management of the Enrichment Program are often best handled by a designee of the Director. Such designee may be for example, a Center member, an Internal Executive Committee, or an Associate Director.

NORCs are strongly encouraged to support clinical and translational research through the Center's services. There are several alternatives to satisfy this expectation. If appropriate for the NORC, the Administrative Core may manage a 'clinical component' within the Center. See Section F. Clinical Component for a description of the requirements and alternatives for the clinical component.

#### Program Management

Applications should describe how the Center will address the following:

- a) coordination of ongoing research between the separately funded projects and the NORC, including mechanisms for monitoring collaborative efforts and for encouraging acknowledgements of the NORC's contributions to the research efforts in all publications arising from the use of core facilities;
- b) establishment and maintenance of internal communication channels among the NORC investigators;
- c) mechanisms for selecting and replacing professional and technical personnel within the NORC, particularly the Director;

d) approach for administering the P/F program, including soliciting applications, the review process, and making funding decisions, as reflected by the general quality of P/F projects submitted with the application; and

e) management capabilities that include fiscal administration, procurement, property and personnel management, planning, budgeting, and other appropriate capabilities.

f) the academic environment in which the NORC activities will be conducted, including the availability of space, equipment, facilities, and the potential for interaction with scientists from other departments and institutions; and

g) the institutional commitment to the Center, including lines of accountability and contributions to the management of the NORC. In addition, the institutional commitment to both new staff members and to investigators responsible for conducting essential NORC functions as well as the commitment to establish new positions specifically designed to enhance the operation of the NORC should be addressed.

### *Center Membership Criteria*

Criteria for designating an investigator as a NORC member should be clearly defined. Subsets of members based on their degree of participation or other quantitative measures are acceptable. Suitable criteria include peer-reviewed independent funding, participation in nutritional sciences and/or obesity-related research, and need for the use of core facilities.

## **D. RESEARCH BASE**

Since the NORC program is aimed at fostering multidisciplinary and interdisciplinary cooperation among a group of funded investigators conducting high quality research involving nutritional sciences and/or obesity, the existence of a strong nutritional sciences and/or obesity research base is a fundamental requirement for, and the most important aspect of, a NORC.

The scientific excellence of the NORC's **research base** (its strengths, breadth, and depth) as well as the relevance and interrelatedness of the funded research projects to nutrition/obesity AND to the central theme(s) or focus of the NORC is a critical component for a NORC. The likelihood of meaningful collaboration among NORC investigators and utilization of the research cores will be evaluated.

For **new** NORC applications, the applicants must indicate how the establishment of a NORC will provide added dimensions and new opportunities for research and increased cooperation, communication, and collaboration. **Renewal** applicants must provide a summary progress report and include progress and accomplishments in the research base in developing multidisciplinary or interdisciplinary, collaborative, and cooperative interrelationships. Judgment of the depth and continuing adequacy of the research base remains a critically important aspect of the evaluation of the NORC application.

Presentation of the research base in the application should be done in two ways: (1) by completing exhibit III; and (2) by providing a descriptive narrative of nutritional sciences and/or obesity-related research activities at the institution and any collaborating institutions. This narrative presentation should be organized to bring out the focus and interrelationships of research being conducted by NORC investigators. Because most, if not all, of the research base will have already undergone separate peer

review, the quality of the individual funded projects will have been established. Important aspects to include in this narrative are (1) interactions and interrelationships of the research efforts (emphasizing the role of the NORC in these interactions); (2) uses/utilization and benefits of core services; (3) plans to develop productive collaboration among NORC investigators; and (4) in the case of renewal applications, the impact that the presence of the NORC has had in regard to the foregoing during the funded grant period. Grants/investigators that are members/utilize other NIDDK Centers should be clearly identified.

Nutritional science and/or obesity-related research projects should be grouped into aggregates of projects with similar overall goals and objectives in the application. Neither in the application nor during a potential site visit (although a site visit is very unlikely) will it be possible for presentations of research in great detail. Appropriate presentation of the research base is important because it will show the research focus of the NORC as well as the interrelationship and potential for collaboration among investigators. Although they can be described in the application, other P30s and/or CTSA(s) should not be included as a component of the NORC research base.

If the institution or the consortium of institutions making up the NORC is the recipients of another NIDDK funded P30 Center Grant, the application must address the potential for overlap, and how duplication of core services, programs, and the research base will be prevented. Membership in more than one NIDDK-funded Center (P30) is permitted; **however, research grants that utilize more than one NIDDK Center (P30) must be high-lighted and the additional Centers used must be identified as presented in exhibits IIIA-D.**

## **E. CORE FACILITIES**

### *Definition*

A biomedical research core in a NORC is a shared facility or resource that provides services needed by NORC investigators. Core services enable Center members to conduct their independently-funded individual research projects more efficiently or more effectively. Cores should be designed to furnish a group of investigators with some technique, determination, service, expertise, or instrumentation that will enhance research progress, consolidate manpower, and contribute to cost-effectiveness. Often, services or techniques can be provided at less cost and potentially higher quality when performed within a core facility as opposed to being done infrequently in an individual investigator's own laboratory. A minimum of two service cores, in addition to the Administrative Core, is required to justify the existence of a NORC.

Cores may be proposed in relation to any acceptable research activity of the NORC, although they usually fall into one of four categories: (1) provision of a technology that lends itself to automation or preparation in large batches (e.g., radioimmunoassay, cell/tissue culture); (2) complex instrumentation (e.g., electron microscopy, mass spectrometry); (3) animal preparation and care; and (4) technical assistance and instruction (e.g., molecular biology, biostatistics).

Cores are not intended to supplant investigator capabilities, but rather to enhance them. When appropriate, core staff should provide instruction for investigators, laboratory personnel, or fellows to learn and then become proficient in technologies that will become part of the repertoire of the laboratory. Teaching complex techniques and methodologies is an important function of a core.

A minimum of two users is sufficient to establish a core; however, a greater number of users generally should be more cost-effective. When a core is proposed for which only the minimum number of users exists, the description of the efforts made (for existing cores in renewal applications) or to be made (for new applications and for new cores in renewal applications) to increase the number of core users, and thus enhance the core's productivity and cost effectiveness, will be carefully considered.

**Renewal** applications should address past use, quality control, cost-effectiveness, and proposed future use of each core for which continuation is requested. Productivity and appropriateness of each core will be judged in part by the list of publications arising from projects using that core. The acquisition of relevant new services and the appropriate deletion of services no longer required will be a factor in the evaluation of existing core facilities. Justification for deletion/addition of new cores must be provided.

The qualifications of the Core Directors and other personnel will be evaluated.

In addition to providing products or services, a core must maintain appropriate quality control and maintain a record of use. **Limited developmental research** is also an appropriate function of a core facility as long as it is directly related to enhancing the function or usefulness of the core and is not an undertaking that should more appropriately be funded through other mechanisms.

The appropriateness and relevance of the proposed **cores** and their modes of operation (such as how requests for services will be prioritized, quality control measures, and how use will be monitored), facilities, and potential for contribution to ongoing research should be described. Applicants should also address the degree to which the cores provide opportunities not otherwise available to the investigators through other available federally funded and/or institutional resources; represent appropriate cost savings/cost sharing advantage; and stimulate the development of new research tools and/or approaches.

## Requirements

### *Use*

The establishment of, and continued support for, a biomedical research core within a NORC is justified solely on the basis of need. The minimum requirement is **significant use by two or more** investigators (including the Core Director if he/she is part of the research base), each with an independently funded peer-reviewed project. Use by two members funded by the same grant does not constitute adequate core use. The **number of projects** being supported will also be considered in the justification for establishing a core. While investigators holding awards from the NORC's P/F program are appropriate users of the core facilities, their use will **not** contribute to the justification for establishing or continuing a core. If there are other NIH centers at participating institutions, potential overlap of cores needs to be addressed in detail.

In renewal applications, any changes should be carefully documented. Cores are encouraged, whenever possible, to enter into cooperative arrangements with established cores in other Centers or resources offering a similar type of service.

### *Core Director*

A Director must be designated for each core. Core Directors should be acknowledged experts with independently funded research programs who will themselves use the core services. Therefore, the

percent effort for the Director requested from the NORC will be relatively low, typically 1.2 to 2.4 calendar months. While it is expected that all core Directors and co-Directors will be Center members, occasionally experts in the specialty area required by the core who are not part of the research base may be appropriate. Sufficient and compelling reasons must be given for appointing any Core Director/co-Director who is not a Center member.

A core Director may also be a junior scientist (who may or may not be a part of the research base) with appropriate expertise that devotes a significant effort to the core. However, an established expert must be included as a consultant to the core when a junior scientist assumes the role of core Director. Furthermore, the career potential of, and institutional commitment to, junior scientists who serve as core Directors will be considered in the review of the NORC (see Part III). The minimum effort for a core director is 0.6 calendar months (5% of full-time professional effort). A core director with requisite expertise may devote a greater effort to the core, and with very strong justification the Core Director could devote up to 12 calendar months. Where appropriate, an established expert in the core activities could also be included as a consultant to the core.

### ***Personnel***

#### ***Personnel:***

Research assistants, associates, analysts, technicians with special expertise, dietitians, nurses, and other qualified individuals are acceptable personnel for a core when appropriate for the volume and type of work anticipated. Research fellows supported by Ruth A. Kirschstein National Research Service Awards (NRSA) are not appropriate personnel for a core.

### ***Facilities***

Arrangements for sufficient space for core activities or for access to appropriate established facilities must be made. Centers are strongly encouraged to enter into cooperative arrangements with cores already established within their institution, or with other NORCs in close proximity, when the existing cores offer the services needed. These arrangements are important whenever greater efficiency or cost savings can be realized by such an agreement. It may be advantageous for a NORC to provide support for appropriate personnel to work specifically for NORC members in an existing facility/core (e.g. transgenic animal core) at the institution. In this case, the designated NORC Core Director must work closely with the parent facility core Director to coordinate services, unless the same individual assumes both roles.

Particularly in new applications, the description of the physical arrangements and instrumentation for the cores should be given special attention. In renewal applications, any changes should be carefully documented. The availability of an NIH-supported CTSA with a metabolic kitchen may be a useful adjunct. In such a case a letter of agreement from either the CTSA Program Director or Principal Investigator must be included with the application.

### ***Charge-back System***

A charge-back system may be developed to allow investigators to utilize any core. Charge-back fees are allowable budgetary items in the investigators' individual research project grants. A system of payment management/accounting must be established such that it is clear to the individual users, the institutional business office, and the NIDDK what the charge-back system covers and how funds recovered are being used. This will enable center investigators to appropriately adjust the budgets on their own grants and ensure accountability.

When a NORC is first established, individual investigator-initiated research project grants may include funds for services that will ultimately be available through the cores. At the time of their next competing continuation (renewal) application or non-competing continuation application (progress report), investigators should describe in detail the interrelationships of the support for services received from the NORC **or remove from their individual research project grant budgets all cost associated with services received from the cores for which they are not charged.** The elapsed time before this adjustment is made generally constitutes a very minor overlap, if any, since it is usually several months before a core is fully functional. Charge back fees to the NORC should be included in the budget of the research project grant once the cores are running since these are a necessary expense and are justified by cost savings.

### ***Operational Plan***

Each core must have a pre-established plan for its operation. Qualifications required for using the core facility and plans for prioritizing use must be clear. Within cores where a primary user is the Core Director or other personnel within the core, the mechanism of prioritization should specifically address the inherent real or perceived conflict of interest. Limited use of cores by established investigators in other fields is encouraged, as is use by trainees, students, and junior faculty. The NORC must decide upon the approach to and extent of training being performed in each core; training is an appropriate and worthwhile activity of a core and is encouraged.

***Management of the core and operational plan:*** The organization and proposed mode of operation of each core should be presented. Included should be a plan for prioritizing investigator use of the core as well as a definition of qualified users. If use by investigators outside the parent institution is proposed, the mechanism by which such investigators will apply and be evaluated and selected should be detailed. The definition of qualified users should not be too narrow. Some minor core use could serve to entice established investigators in other scientific disciplines into the field of nutritional sciences and or obesity research. Any proposed, ongoing or completed developmental efforts should be described. If the core is used to train investigators in special techniques, the mechanism for this training should be included.

Any core with a minimum number of users must develop plans to broaden the number of core users. Such plans should be outlined for any core that is not extensively used but is considered essential by the NORC administration.

***Renewal applications:*** Information relative to cores in renewal applications should generally cover all of the same points as initial applications. In addition, past performance and accomplishments should be described. The effect of the service provided by a core on investigator productivity and cost-effectiveness should also be addressed.

## **F. CLINICAL COMPONENT**

NORCs are encouraged to provide support for clinical and/or translational research in nutrition and/or obesity. If included as a part of the NORC, the potential for, or past efforts of, development of any clinically-relevant specialized services, applicable and useful for NORC members will be evaluated. The relationship of the research themes to the clinical research component (either as a 'Clinical Component' of the Administrative Core, integrated into biomedical cores, or through another means), if provided, will also be evaluated.

The support of clinical/translational research may be accomplished in one or more ways. Each NORC should provide a description of how the center will foster and support clinical investigations and applied translation. NORCs may support clinical/translational research as follows:

- a. One or more clinical research cores: clinical research services may be provided for and budgeted through stand-alone research cores
- b. A **Clinical Component**: services can be provided and budgeted for through the administrative core.
- c. A combination of a and b.
- d. In a way other than those above that meets the needs of the center

Applications should describe how their center will foster and support clinical investigations and applied translation under the 'clinical component' section of the application or explain why a clinical component is not needed as a part of the NORC center to support the research base of the NORC. If the NORC will provide clinical research services through one or more stand-alone research cores, applications should describe what those services are and how they will facilitate clinical research within the text of the 'clinical component' section of the application.

If the NORC will not support clinical research through one or more biomedical research cores, a 'clinical component' may be managed and funded through the Administrative Core. Services within the 'clinical component' may include, for example, support of a biostatistics consultation; assist with clinical study design; foster collaboration among researchers; aid in recruitment of subject for clinical studies; provide data entry support for epidemiological studies; or provide modest funding for tissue, DNA, or serum storage. The clinical component may serve as the bridge between Center clinical and basic science investigators. In addition, staff within the clinical component may aid investigators in effectively addressing NIH policies and reporting requirements concerning inclusion of women, children, and ethnic/minority participation in clinical studies; data and safety monitoring requirements; and educational requirements for the protection of human research participants.

A NORC may also propose to support a combination of both clinical research core(s) and a 'clinical component' within the Administrative Core. Services should be budgeted through the core in which they would be performed.

Although there is no separate budget category for the 'clinical component' (it can be supported by the Administrative Core or in other cores established in the NORC), the services offered and the qualifications of the personnel requested within the overall NORC application as well as the number of physician scientists, and perhaps basic researchers, who will make use of available/relevant clinical component services will be evaluated.

## **G. PILOT AND FEASIBILITY STUDIES**

Although research projects associated with a NORC are funded from other resources, there is one exception--pilot and feasibility (P/F) studies.

### **Definition**

P/F project funds provide modest support (typically \$10,000 to \$50,000) for new initiatives or feasibility research studies for a limited time to enable eligible investigators to explore a nutritional sciences and/or

obesity-related research concept. P/F projects are intended to provide support for investigators to collect preliminary data sufficient to support a grant application for independent research support. P/F studies may (1) provide support for new investigators; (2) encourage investigators from other areas of biomedical research to use their expertise for nutritional sciences and/or obesity research; and (3) allow established nutritional sciences and/or obesity-investigators to pursue high impact/high risk projects or project that are a **significant departure** from their usual work.

P/F project support is not intended for the extension of projects by established investigators for which it would be appropriate to submit a research project grant application. P/F funds are also not intended to merely fund or supplement ongoing research of an established investigator.

### **Eligibility Criteria**

Investigators eligible for P/F funding fall into four categories:

- (1) new investigators without current or past NIH research project support (R01, P01 or R24) as a Principal Investigator. New investigators current or past support from other sources must have been modest, i.e., typically no more than \$75,000 per year, exclusive of salary. Institutional start-up funds are excluded.
- (2) established, funded investigators with no previous work in nutritional sciences, and/or obesity who wish to test the applicability of their expertise to a nutritional science and/or obesity-related problem;
- (3) on rare occasions, established investigators in nutritional sciences and/or obesity-related areas who wish to test the feasibility of a new or innovative or high-risk idea which constitutes a significant departure from their funded research. (Generally, this does not mean repeating an experiment using just a different cell type or animal model.); and
- (4) investigators concerned with the development and evaluation of innovative, exportable and effective materials, methods, and programs to translate and disseminate research in biomedical and behavioral sciences to patient healthcare.

**The NIDDK expects that the majority of P/F project investigators will fall into the first category and only in exceptional circumstances will category 3 investigators be supported.**

Trainees who are recipients of an NRSA individual award (F32) or are supported by an institutional training grant (T32) are eligible for P/F funds **only** if they are in their last year of training, have had at least one year of research laboratory experience at the postdoctoral level, and have suitable expertise and independence to design and carry out the planned experiments. Trainees requesting P/F funds should have a commitment from a senior scientist to sponsor the project. P/F funds cannot be used to supplement NRSA stipends, but may be used for supplies, technical support, special services, etc.

There is no citizenship requirement for P/F recipients, BUT visiting scientists with whom the NORC investigators will not have a long-term collaborative relationship are not considered strong candidates for support. Individuals whose intention is to remain involved in nutritional sciences and/or obesity-related research, either in the U.S. or elsewhere, may be supported by P/F funds. Individuals who are intending to remain in the U.S. as citizens or permanent residents may be supported by P/F funds as long as they otherwise meet the eligibility criteria above.

Each P/F project application should clearly identify the eligibility of the investigator using one of the four categories listed above. A proposed P/F project should clearly delineate the question being asked; present a testable hypothesis; detail the procedures to be followed; and discuss how the data will be analyzed. The research must involve a nutritional sciences and/or obesity-related topic relevant to the current focus of the NORC or involve an avenue of new research into which the NORC will be moving.

P/F projects that evaluate the effectiveness of a model program developed for translating research in biomedical and behavioral science into routine clinical care are encouraged. In view of the disproportionate occurrence of obesity and its associated health risks in minority populations, the NORC is encouraged to develop activities reflecting the expertise of the Center and directed at the problems of one or more of these populations.

The P/F studies should be submitted for Center review in the general format of NIH research pilot/planning project applications (R21). Projects should be focused because funding for these studies is modest, usually ranging from \$10,000 to \$50,000 per year. They are limited to 3 years or fewer. Investigators may receive P/F support only once in any five-year funding cycle. P/F studies may be supported for research projects in four general areas: (1) biomedical; (2) epidemiological; (3) clinical; and (4) translational research.

To broaden the scope and reach of the NORC P&F program, a Center may propose to serve a wider scientific community by expanding the NORC P&F program to a different institution(s). Expansion of the P&F program to an affiliated institution/hospital is allowed. In general, NIDDK currently expects NORCs to allow investigators at affiliated hospitals or institutions to participate in the Center P&F program. Applicants may request funds to expand their P&F program to researchers at non-NORC institutions, and the applicant should provide details on how F&A costs for P&F grants will be handled with the partnering institution(s).

### **Administration of P/F Program**

While the management of the P/F program is left to the discretion of the NORC, it must include the elements listed below.

1. A mechanism must be established to advertise the availability of P/F funds.
2. A mechanism for the scientific merit review of P/F projects must be established. At least one reviewer from outside the NORC must be used to evaluate each application. Details of handling the review will be left to the NORC, although all reviewers should assign priority scores in accordance with the NIH system. Copies of all of the projects with written documentation of the reviews, priority scores, and final action should be retained by the NORC. These records should be available to outside reviewers and NIH staff, if requested.
3. A mechanism for making recommendations to the NORC Director for initial funding decisions should be outlined.
4. A mechanism for the oversight and review of ongoing P/F projects should be developed as a requirement for a second or third year of funding.
5. A mechanism to terminate P/F projects must be established. Studies may be terminated by the NORC administration before their approved time limit for various reasons such as (1) the investigator receives outside funding for the project; (2) the project was found not to be feasible; or (3) the investigator left the

NORC institution. When such situations result in the termination of a project, the NORC may make new awards for P/F projects with the remaining funds or supplement other ongoing projects.

6. A plan for tracking the success of the P/F program should be established. A record of scientific publications, abstracts, and grant applications submitted/funded, as well as information on whether the investigator remains in nutritional sciences and/or obesity-related research is important. Staff of the NIDDK use this record to determine whether the P/F program is a useful component of the Center, serving to encourage investigators to remain in nutritional sciences and/or obesity research.

Each NORC Director is strongly encouraged to involve the External Advisory Board in the management of the P/F program. P/F grant recipients are encouraged to collaborate or consult with any biostatistics component supported by the NORC or otherwise available at the applicant institution and to utilize the core facilities or the clinical component of the NORC.

General guidance for support of P/F studies should not exceed \$150,000 per year in the aggregate. Prior approval from the NIDDK is necessary to transfer funds from the P/F category to the cores or from the cores to the P/F program.

For **both** new and renewal applications, P/F projects will be evaluated in the context of the P/F program as a whole. Of key importance is whether each applicant is eligible (see Part I-G of these guidelines), whether the proposed hypotheses are reasonable, whether the project relates to the focus of the NORC, whether the project appears feasible, whether the center encourages 'high-risk', innovative ideas through their P&F program, and whether any P&F studies have progress to submission of an application for funding.

In **new** applications, the P/F projects will be assumed to be the best selections made using the proposed evaluation procedures described in the application. In **renewal** applications, the submitted P/F projects will be assumed to be the best selections made using the Center's existing review procedures as described in the application.

### **Budget for the P & F Program**

The requested level of funding for the P/F program should be based on the quality of the submitted P/F projects, the proposed method for management and review, and the study section's assessment of the potential needs and opportunities for P/F studies at the NORC.

**Renewal** applications may request an increase in P/F support, to maintain the current level of support, or to reduce the level of support based on the performance of the NORC's overall P/F program. The request should be justified by: (1) the extent to which P/F funds were fully utilized during the previous project period; (2) the extent to which awards were made to investigators who fully met the eligibility criteria for P/F project support as outlined previously; (3) the extent to which the awards made are considered to be relevant to the current or future research themes of the NORC; (4) the extent to which previously supported P/F projects were successful (e.g., the P/F recipients are currently funded; a new investigator was attracted into nutritional sciences or obesity-related research; or peer-reviewed publications or presentations resulted); and (5) whether the P/F recipients have remained in nutritional sciences or obesity-related research.

## **H. NAMED NEW INVESTIGATOR (OPTIONAL)**

Each NORC may provide salary support for a P/F project recipient whom they designate a Named New Investigator. Support for this individual is generally for 2 years, but may be extended to 3 years, and cannot exceed \$75,000 per year, additional appropriate fringe benefits, and 6.0 to 12.0 calendar months effort. These funds are included in the Administrative Core budget. The individual selected should be a junior investigator who a) meets the P/F project eligibility criterion and b) is a permanent resident or US citizen. Individuals are eligible only once for this support. Subsequent candidates for this position are nominated by the Center and reviewed by its External Advisory Board. Appointment of the Named New Investigator is contingent upon the concurrence of the External Advisory Board and the NIDDK program director.

The Named New Investigator will be reviewed separately. The associated pilot study must have been evaluated in a manner similar to the P/F projects in general. In a **renewal** application, the progress of previous Named New Investigators will be considered, i.e., whether their P/F projects led to publications and/or grant awards, and whether the investigator has remained in nutritional sciences or obesity-related research at the NORC or elsewhere.

## **I. ENRICHMENT PROGRAM**

The NORC grant can provide limited support for an enrichment program under the auspices of the Administrative Core. The NORC enrichment program should be designed to advance translational research in nutritional sciences and/or obesity, and to promote scientific exchange among investigators with research interests in these topic areas, and to enhance interactions between nutrition and obesity researchers and investigators from other fields with relevant expertise. The enrichment program can support activities such as seminars, guest speakers, visiting scientists, consultants, and workshops. Applicants should describe any training opportunities afforded by the NORC participants, and document ways the Center may facilitate, enhance or foster the institutional training environment.

Center applicants should provide information on related NIDDK T32 programs at the Center institution(s), and describe how the NORC will help to integrate, facilitate and enhance activities of T32-supported trainees. A letter from the PI of any related NIDDK-funded T32 at the Center institution should be included that acknowledges and details how the PI of the T32 intends to promote cohesive interactions between the two programs.

Training postdoctoral fellows to conduct research in nutrition and/or obesity may be an associated activity of a Center. Mini-sabbaticals to allow Center investigators to enhance their scientific and technical expertise are allowable expenses. While stipends for fellows cannot be funded from the Center, the establishment of a Center should provide an enhanced environment for research training. Limited travel support may be requested to allow NORC investigators to present scientific findings, to learn new laboratory techniques, to develop new collaborations, or to engage in scientific information exchange.

## **J. COLLABORATION BETWEEN CENTERS**

Collaborative efforts between investigators in the various centers (at the applicant institution or other institutions) supported by the NIDDK, NIH, and other federal and non-federal sources are encouraged. These efforts may involve sharing scientific resources, distributing educational information, or sharing

seminar program speakers. The process for addressing overlap of the research base/cores must be described.

**K. BUDGET**

The appropriateness of the budgets requested for all of the cores, the P/F program, and for enrichment activities will be evaluated. Total Direct Costs are limited to \$750,000 per year (including P/F program funds). At times the requested amount may exceed this limit due to facilities and administration costs incurred by contractual arrangements.

**PART II**  
**APPLICATION PROCESS:**  
**FORMAT AND CONTENT**

## **A. GENERAL INSTRUCTIONS**

Applications for NORCs are accepted only in response to a Request for Applications (RFA) published in the NIH Guide for Grants and Contracts.

The receipt date for applications is indicated in the RFA. Individuals from institutions with an interest in applying for a NORC grant should contact NIDDK program staff as early as possible in the application preparation process. This consultation is crucial. Applicants should not construe advice given by the NIDDK staff as assurance of a favorable review and/or possible funding. The staff will not evaluate or discuss the merit of the scientific aspects of the application.

Prospective applicants are asked to submit a **letter of intent (LOI)** to the address listed in the RFA that includes the following information:

Descriptive title of proposed research

Name, address, and telephone number of the PD(s)/PI(s)

Names of other key personnel

Participating institutions

Number and title of this funding opportunity

Grant applications must be submitted using the most recent PHS Form 398. Submit the signed original application, including the Checklist, plus three signed photocopies in one package to:

Center for Scientific Review

National Institutes of Health

6701 Rockledge Drive, Suite 1040, MSC 7710

Bethesda, MD 20892-7710 (U.S. Postal Service Express or Regular mail)

Bethesda, MD 20817 (Express/Courier Non-USPS Service)

At the time of submission, two additional copies of the application and all copies of the appendix material must be sent to:

Francisco O. Calvo, Ph.D.

Chief, Review Branch

NIDDK

6707 Democracy Boulevard, Rm. 752, MSC 5452

Bethesda, MD 20892-5452

(for express/courier service: Bethesda, MD 20817)

The arrangement of materials should follow both the instructions in the PHS Form 398 application kit and the more specific guidance detailed below and in the RFA. Applications not in accordance with Center guidelines will be returned to the applicant.

Applicants should keep in mind that the written application is the basis for the merit review. Particular attention should be given to the format of the application. Awards for Center grants are for five-year project periods. Basic information useful for preparing the application follows. Applicants may also consult with NIDDK staff concerning the technical aspects of preparing the application.

**\*\*\*\*Applicants should read Part III of these guidelines to understand the criteria used for evaluating NORC applications. \*\*\*\***

## **B. SPECIFIC INSTRUCTIONS –FORMS (PHS Form 398)**

### Face Page:

Items 1-14 (See PHS Form 398)

NOTE: Awards for NORC grants are made for **five year** project periods.

### Form Page 2:

Description, Project/Performance Sites (self-explanatory)

Number the pages consecutively throughout the application.

Senior/key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells (follow 398 instructions)

### Form Page 3:

Table of Contents: Provide a Research Grant Table of Contents following the basic format shown in the 398 kit but modified to be appropriate for the items submitted for a center application.

### Form Page 4:

Provide a detailed budget for initial budget period (See Exhibit I).

Separate budgets for each core and for the clinical component, if requested, should immediately precede the narrative of that section, using form page 4.

### Form Page 5:

Budget for Entire Proposed Project Period

**The total funds requested for the P/F grant program should be included in the "other expenses" category of the budget for the Administrative Core.** Except for named new investigators, salary support for P/F projects is discouraged. The individual P/F project budgets should be included before the narrative of each P/F project using PHS Form 398, form page 4, if desired.

### Biographical Sketch Format Page:

Provide biographical sketches for all NORC investigators (key personnel, research base investigators, consultants, and collaborators). Biographical sketches for principal investigators on P/F projects should be included with the P/F project. Follow the current NIH Form 398 instructions.

A summary of the distribution of percent of professional effort for this application is useful for reviewers and may be included after the Biographical Sketches. (See Exhibit II for suggested format).

### Research Base

A summary of the current and pending support for all NORC investigators, including percent efforts, should be presented as depicted in Exhibits III-A through-D, with nutritional sciences and/or obesity-related research support listed first followed by non-nutritional sciences or obesity-related support. K-series awards may be included here. Other P30s/CTSAs, Institutional Training Grants (T32 or T35) and Individual Fellowship Awards (such as F31s or F32s) are not considered part of the research base but may be listed in a separate category in III A and B. U awards (Cooperative Agreements) may be listed only if they use one or more cores/services.

Grants/projects whose research funding will terminate before the NORC funding period will begin should be included in a separate list. Grants that have been or will be submitted for renewal should be listed in the 'pending' category.

#### Resources Format Page:

Facilities and Major Equipment: general overall description of research facilities (space, equipment, collaborations, etc.) and the major, shared pieces of equipment to be used by Center members should be provided. Specific core facilities, equipment, and special resources should also be listed in each core component.

### **C1. SPECIFIC INSTRUCTIONS - Research Plan (PHS Form 398, Section V)**

*For Initial (NEW) applications, refer to this section. Renewal applications, see section C2—RENEWAL.*

#### **Introduction to the Center – Background and Overview (12 Pages) + Exhibits I and II**

Provide a background and overview of the NORC. Discuss how the NORC will foster nutrition and/or obesity research within the institution/consortia. Address the likelihood of meaningful collaborations among NORC investigators. A description of the focus/themes of the NORC and any unique aspects should be presented. Discuss how the focus/themes of the NORC relate to the proposed NORC cores/services.

Provide an outline of the relationship of the NORC to the institution and the reporting lines of the NORC Director to appropriate institutional officials. If this is presented in diagrammatic form, also provide a brief explanation in narrative form. If appropriate, describe how the NORC will relate to/collaborate with other NIDDK and NIH programs, such as a CTSA, other P30s, and/or relevant training programs. Discuss how the NORC will provide added value to the institution/consortia and the research base/NORC members. While facilities (space, equipment, library, etc.) must be clearly described for each element of the application, include a more global description of the overall facilities and a statement regarding institutional commitment to the NORC.

Describe the mechanism for becoming a member of the NORC. Include a discussion of the criteria for designating an investigator as a NORC member. If there are various levels of membership, such as full member or associate member, describe the levels of membership and note the criteria for achieving each level of membership and the benefits to an investigator for each level of membership.

#### **Administrative Core (New applications)—12 pages**

Include a budget for the Administrative Core on an NIH Form 398 budget page (this page does not count in the 12 page limit of the administration core description) with a comprehensive budgetary justification. Most Centers find that the size and complexity of a NORC warrants inclusion of a full or part-time program administrator. Other budgetary items that, if requested, should be included here are funds for enrichment programs, travel funds for the PI and the program administrator to attend the annual meeting of NORC directors, and salary for the Named New Investigator. The P/F project of the Named New Investigator should be included in the P/F grant program.

Provide a description of the administrative/oversight structure of the NORC, including: chain-of-command, committee structures (e.g., Internal Advisory Committee; P/F review; other oversight or management committees), and oversight of cores, the clinical component (if applicable), and the enrichment program. In the event of a consortium arrangement, chain-of-command across the participating organizations needs to be described in detail.

Provide a brief narrative describing the qualifications of the Director and associate Director (or co-PIs if the multiple PI option is selected), and a plan for replacing the Director should this become necessary.

Describe how an External Advisory Board will be established. List the areas of expertise necessary for inclusion on the External Advisory Board and discuss what functions the external advisory board will be asked to perform. For new applications, do **NOT** specify the names of the individuals whom you plan to recruit to serve in this capacity.

Describe any functions that the Administrative Core will provide for NORC members, such as statistical support, clinical studies design, or recruitment services. There is no requirement that the NORC Administrative Core provides any set list of services, but if services are provided and are budgeted for in the Administrative Core, they should be discussed under the Administrative Core.

Include a description of the mechanism for monitoring budgetary overlap between the research projects included in the research base and the funds for the core facilities of the NORC. Describe a mechanism to monitor the budgetary adjustments made necessary by the use of core services. This will ensure that NORC investigators using cores are able to provide a satisfactory explanation of their relationship to the NORC and their inclusion of charge-back fees to the cores in their individual grant budgets.

#### **Clinical Component (New applications)- 6 pages**

Describe plans to support clinical and/or translational nutrition and/or obesity research, if they will be a part of the NORC. See Part I, Section F. ‘Clinical Component’ for instructions. If a ‘clinical component’ is to be supported through the Administrative Core, include funds in the budget for the Administrative Core.

#### **Enrichment Program (New applications)--6 pages**

Describe plans for the enrichment program in as much detail as possible. Include funds for the enrichment program in the budget for the Administrative Core. Refer to Part I, Section H.

#### **Research Base (New applications)--6 page introduction + Exhibits III, IV + 1 page narrative description of each research project**

Include an overview of the current nutritional sciences and/or obesity-related research activities at the institution. An appropriate and clear presentation of the ongoing research base is critical since it will show the research focus of the NORC and the interrelationships and potential for collaborations among investigators. Since the research base projects will already have been peer-reviewed, the quality of the individual funded projects has been established and will not be re-evaluated.

Provide sufficient detail to assist reviewers in judging the extent and the inter-relatedness of ongoing research. Emphasize the anticipated impact of the establishment of a NORC on the research base. Include an indication of how the establishment of a NORC will provide added dimensions and new opportunities for nutritional sciences and/or obesity-related research, along with increased cooperation, communication, and collaboration among investigators.

Overly detailed descriptions of the research base projects are discouraged; therefore the presentation of the research base in the application is best done in two ways: (1) by providing information in a format such as that shown in Exhibit III, and (2) by providing a narrative description of one page (or less) per research project in which the duration of award, a short description of the goals and objectives, and a short description of the symbiotic relationship to and from the NORC are described. Limiting each description to less than one page is encouraged, but not always feasible. These narratives should include: (1) grant numbers, titles, and a few descriptive sentences, and (2) a list of the core(s) which will be used.

Include a brief sentence indicating what aspect of the research justifies the use of each core. ONLY those grants awarded to investigators at the applicant institution or the applicant consortium, not to collaborators at other locations, should be included in the description of the research base. It is particularly important to provide a few sentences indicating the relatedness of a cited grant to nutritional sciences and/or obesity research when this is not readily apparent from the title of the grant.

For institutions with more than one NIDDK-funded P30 Center, research grants that utilize other Centers in addition to the NORC should be clearly identified. **Annual directs costs for grants whose research aims fall into more than one distinct NIDDK Center may be divided/reduced proportionately, e.g. 50% NORC and 50% Diabetes Research Center**.

List grants related to nutrition/obesity first (Exhibit III-A), followed by pending nutrition/obesity-related support (Exhibit III-B), and then other non-nutrition/obesity-related research support (Exhibit III-C) and other ‘pending’ research support (Exhibit III-D). Grants/projects whose research funding is in a no-cost extension and/or will terminate before the NORC funding period will begin should be included in a separate list.

For institutions without other NIDDK-funded P30 research centers, group nutritional sciences and/or obesity-related research projects into aggregates of thematically-related studies with similar overall goals and objectives. A majority of the research base should have a central focus or theme (or themes), which is related to nutritional sciences and/or obesity.

Present any collaborative efforts using Exhibit IV, although pre-existing extensive collaborations are not a prerequisite for new applications.

(Note: Exhibit V- Publications does **NOT** apply for NEW applications.)

### **Biomedical Research Cores (New applications)--12 pages + Exhibit VI-A + budget for EACH core**

Present each core separately. Provide an overview of the purpose and structure of the core and its relationship to the Center’s focus/themes. Include the rationale for establishing the core, the facilities to be used, and the activities/services of the core. Provide short descriptions of the services provided and the projects of the investigators who will use the core. Give special attention to the description of the physical arrangements and instrumentation for the core.

Present the organization and proposed mode of operation of each core. Describe plans for:

1. assuring quality control
2. prioritization of investigator use
3. monitoring core use
4. adapting to new technology and to the needs of the NORC members.

Include a definition of qualified users. Provide a list of funded Center investigators who will use the core and the expected extent of their proposed use. Use sample Exhibit VI-A to present how cores would be used. Emphasize the anticipated benefits that investigators will derive from using core facilities.

Limited use of the core by established investigators in other fields is encouraged, but rules to regulate this use should be defined. If the core is used for training, detail the approach to and extent of the training. Use of the core for training Center members is encouraged. Describe any plans to use the core for limited

developmental research, including the relevance of this research to core services, effectiveness, and adaptability.

Since NORCs are strongly encouraged to enter into cooperative arrangements with established cores at the applicant institution or at other NORCs offering a similar type of service, describe the nature of any cooperative arrangements, the prioritization plan, methods for monitoring utilization, and procedures to assure that duplication or redundancies of effort, services and resources will be avoided.

For each core, include a budget with detailed justifications for: (1) the initial budget period, and (2) entire project period. Detail the qualifications of the core Director and the duties and qualifications of other personnel, including technical support staff. In the event a core Director is not an established investigator (see Part I), highlight the institutional commitment to and career plans for the individual.

When cores use human subjects or animals, include the information required by the 398 form.

**Pilot and Feasibility Studies Program (New applications)—6 pages discussion of P&F program + as well as 12 pages for up to four currently funded or approved P/F project being presented** (3 pages for EACH project)

Provide a composite budget with justifications for (1) initial budget period, and (2) proposed future years. The actual budget request for the P/F program should be listed in the "other expenses" category in the budget for the Administrative Core.

Describe the management plan for the P/F grant program, including both internal and external review mechanisms along with an outline of the plans for future years of the P/F Program. This should include how applications will be solicited, reviewed, awarded, and, if required, terminated.

Do not describe all of the proposed P/F projects. Describe up to four P/F projects that best represent the P/F work of the Center. These initially proposed P/F projects must have been reviewed by the NORC in the manner proposed for review of future studies so that only those considered to be of the highest quality are included in the grant application. Indicate the number of applications that were received and evaluated. An assessment of the relevancy of the proposed individual P/F projects to the NORC's specific goals and objectives is important.

Clearly indicate the **Named New Investigator** if such a position is being requested and how he/she was selected. Salary support for this position is to be included in the Administrative Core.

P/F projects will be reviewed as a group by the IRG. For each P/F project proposed provide: (3 pages)

- a) budget with justifications for: (1) initial budget period, and (2) entire proposed project
- b) justification for eligibility of the P/F project (how it fits with the NORC's goals)
- c) justification for eligibility of the P/F investigator (see Part I-G)
- d) justification for core use
- e) description of the project.

**Also, see Part II-E for Specific Instruction regarding the Budget.**

## **C2.SPECIFIC INSTRUCTIONS for renewal applications- Research Plan (PHS Form 398)**

*For Renewal applications, use this section. For Initial applications see Part II-C1-NEW.*

### **Introduction to the Center – Background and Overview (12 Pages) + Exhibit I and II**

Provide an overview and brief history of the NORC. Provide a description of the research focus of the NORC as well as any unique aspects of the Center. Describe any changes in the research base, the membership, or the focus of the Center, and how such changes affect the NORC or are attributed to the NORC, as well as a synopsis of accomplishments and collaborations that have developed. A description of the focus/themes of the NORC and any unique aspects should be presented. Discuss how the focus/themes of the NORC relate to the proposed NORC cores/services, including any changes over the past funding period.

Provide an outline of the relationship of the NORC to the institution and the reporting lines of the NORC Director to appropriate institutional officials. If this is presented in diagrammatic form, also provide a brief explanation in narrative form. If appropriate, describe how the NORC will relate to/collaborate with other NIDDK and NIH programs, such as a CTSA, other P30s, and/or training programs. Discuss how the NORC will provide added value to the institution/consortia and the research base/NORC members. While facilities (space, equipment, library, etc.) must be clearly described for each element of the application, include a more global description of the overall facilities and a statement regarding institutional commitment to the NORC.

Describe the mechanism for becoming a member of the NORC. Include a discussion of the criteria for designating an investigator as a NORC member. If there are various levels of membership, such as full member or associate member, describe the levels of membership and note the criteria for achieving each level of membership and the benefits to an investigator for each level of membership.

Centers are encouraged to adapt their cores/and or core services to meet the needs of their user base. Describe the process for monitoring the needs of the user base, core utilization and use of core services. If a core supported during the previous funding period was discontinued, briefly describe the core and provide details on how and why that decision was made. If a new core was added/spun off or the services provided in that core differ substantially from those supported during the prior funding period, the rationale should be discussed within the narrative of the relevant biomedical research core(s).

### **Administrative Core (Renewal)- 12 pages**

Include a budget for the Administrative Core with a comprehensive justification. In addition to the Center Director and co- or Associate Directors (or co-PIs if the multiple PI option is selected), include a full or part-time administrator as well as funds for the enrichment program, travel funds for at least two persons to attend the annual meeting of NORC directors, and salary for the Named New Investigator. The P/F project of the Named New Investigator should be included in the P/F program.

Include a brief narrative describing the qualifications of the Director and associate Director (or co-PIs if the multiple PI option is used). It is important to include a plan for replacing the Director should this become necessary.

Provide a description of the administrative structure of the NORC, including chain-of-command, committee structures (e.g., Internal Advisory Committee; P/F review; other oversight or management committees), and core and clinical component oversight.

Since the External Advisory Board is already established, list the names of the members and their areas of expertise. Also, indicate any changes in membership that have occurred during the previous funding period or are anticipated for the upcoming funding period.

Describe any functions that the Administrative Core will provide for NORC members, such as statistical support, clinical studies design, or recruitment services. There is no requirement that the NORC Administrative Core provide any set list of services, but if services will be provided and are budgeted in the Administrative Core, they should be discussed under the Administrative Core. Describe any changes made to the Administrative Core over the past funding period.

Include a description of the mechanism for monitoring budgetary overlap between the research projects included in the research base and the funds for the core facilities of the NORC. Describe a mechanism to monitor the budgetary adjustments made necessary by the use of core services. This will ensure that NORC investigators using cores are able to provide a satisfactory explanation of their relationship to the NORC and their inclusion of charge-back fees to the cores in their individual grant budgets. Include a description of the mechanism for monitoring budgetary overlap between the research projects included in the research base and the funds for the core facilities of the NORC. Describe the mechanism to monitor the budgetary adjustments made necessary by the use of core services.

Renewal applications should use table VII to present a master list of all publications resulting from research that was supported by the NORC during the past funding period. List each publication only **once. Include peer-reviewed publications ONLY and underline, bold, or otherwise indicate those authors who are NORC members.** Include PMCID numbers, as appropriate. Invited papers, book chapters, abstracts, symposia proceedings, etc. may be included, but must be clearly identified as such as in a separate category/list. Include only publications that were published during the previous 5-year funding period.

#### **Enrichment Program (Renewal)--6 pages**

Briefly describe the enrichment program and indicate the program's value to NORC members. Indicate how the program has grown or been adapted to better serve Center members' needs during the past funding period.

Describe future plans for the enrichment program. Include funds for the enrichment program in the budget for the Administrative Core.

#### **Clinical Component (Renewal)--6 pages**

Describe plans to support clinical and/or translational nutrition and/or obesity research, if this is a part of the NORC. See Part I, Section F. Clinical Component for details. Indicate how the clinical component and/or clinical research cores have grown or been adapted to better serve Center members' needs during the past funding period.

Describe future plans for supporting clinical research. If the clinical component is to be supported through the Administrative Core, include funds within the budget for the Administrative Core.

**Research Base (Renewal)--6 page introduction + sufficient pages for Exhibits III, IV, V + 1 page narrative description for each research project**

Provide a summary progress report that encompasses the following areas:

1. interactions and interrelationships of the research efforts;
2. uses and benefits of core services; and
3. plans to develop productive collaboration among NORC investigators.

Describe the evolution of the research base and the NORC's contribution to this ongoing development.

Present the research base in two ways: (1) by providing information that will assist in the review of the application, in the format shown in Exhibits IIIA-D, and (2) by a descriptive narrative of the nutritional sciences and/or obesity-related activities at the applicant institution and any collaborating institutions. Grants/projects whose research funding will terminate before the NORC funding period will begin should, if included, be incorporated into a separate list. Grants that will be or have been submitted for renewal should be listed in the 'pending' category. Exhibits III-A through D do not substitute for the information contained on the Biographical Sketches requested in the 398 application kit, but aid greatly in the review process.

Organize the narrative presentation of the research base to emphasize the focus of the research and the interrelationships of the NORC investigators. **Provide a narrative description of no more than one page per research base investigator; try to limit each to less than one page.** These narratives should include: (1) the grant number, title, and a few descriptive sentences, including a description of how the research is relevant to nutrition and/or obesity, and (2) a list of the core(s) used with a brief sentence indicating what aspect of the research justifies the use of each core. Include ONLY those grants awarded to investigators at the applicant institution or consortium, not to investigators at other locations, in the description of the research base. It is particularly important to provide a few sentences indicating the relatedness of a cited grant to nutritional sciences and/or obesity research when this is not readily apparent from the title of the grant.

For institutions with more than one NIDDK-funded P30 Center, research grants that utilize other Centers in addition to the NORC should be clearly identified. **Annual directs costs for grants whose research aims fall into more than one distinct NIDDK Center may be divided/reduced proportionately, e.g. 50% NORC and 50% Diabetes Research Center.**

List grants related to nutrition/obesity first (Exhibit III-A), followed by pending nutrition/obesity-related support (Exhibit III-B), and then other non-nutrition/obesity-related research support (Exhibit IIIC) and other 'pending' research support (Exhibit IIID). Grants/projects whose research funding is in a no-cost extension and/or will terminate before the NORC funding period will begin should be included in a separate list.

Document collaborative efforts using the format shown in Sample Exhibit IV to aid in the review process.

Use table V to present a master list of all publications resulting from research that was supported by the Center during the past funding period. List each publication only **once**. **Include peer-reviewed publications ONLY and underline, bold, or otherwise indicate those authors who are NORC members.** Include PMCID numbers, as appropriate. Invited papers, book chapters, abstracts, symposia proceedings, etc. may be included, but must be clearly identified as such as in a separate category/list. Include only publications which have been published during the previous 5-year funding period. Also, **the**

**NORC should have been credited as a resource in all publications.** This acknowledgement provides evidence to the study section, and the NIDDK, of core use. For any publications that received Center grant support but did not cite the Center grant number, use an asterisk (\*) at the beginning of the publication listing.

**Biomedical Research Cores (Renewal)--12 pages + Exhibit VI-B + budget for EACH core**

Present each core separately. Discuss the purpose, structure, facilities, and services that the core will provide and its relationship to the Center's focus/themes. For renewal applications, information regarding the cores should generally cover the same points as in the initial application as well as information on past performance of the core and its usefulness to NORC investigators. Include the impact of the core services on investigator productivity in meeting stated goals and objectives and in promoting cost effectiveness. Emphasize the past and future benefits to investigators derived from the use of core facilities. If a new core was added or spun off, provide the rationale and method for developing that core.

For cores that provide consultation/informational services describe the added value of those services and communication with Center Director(s) and members. Describe how those services will be promoted to the members. If a core is located (physically or virtually) at multiple or consortium locations, describe the communication/leadership process and past/future utilization by core members located at other sites within the consortium.

Include budgets with comprehensive budgetary justifications for: (1) initial budget period, and (2) entire proposed project period.

Detail the qualifications of the core Director and the duties and qualifications of other personnel, including technical support staff. In the event a core Director is not an established investigator (see Part I), highlight the institutional commitment to and career plans for the individual.

Detail the objectives in continuing/establishing the core facility and describe the core. The description should include the facilities used as well as the activities of the core. Provide short descriptions of the services provided and the projects that use the core. Document any changes that have taken place since the last competitive review.

Provide details of core management, including plans for:

- 1) assuring quality control
- 2) prioritization of investigator use (Within cores where a primary user is the Core Director or other personnel within the core, the mechanism of prioritization should specifically address the inherent real or perceived conflict of interest.)
- 3) monitoring core use
- 4) adapting to new technology and to the needs of the NORC members.

Document past use of the cores using sample Exhibit VI-B. Include a list of the investigators who will use the core as well as the extent of their use. If the core is used for training, detail the approach to and extent of the training. Use of the core for training Center members is encouraged.

Describe any developmental research performed in the core and indicate its relevance to the services offered by the core.

Since NORCs are strongly encouraged to enter into cooperative arrangements with established cores at the applicant institution or at other NORCs offering a similar type of service, describe the nature of any cooperative arrangements, the prioritization plan, methods for monitoring utilization, and procedures to assure that duplication or redundancies of effort, services and resources will be avoided.

Discuss publications arising from use of the core (with references to Exhibit V) as appropriate.

Provide information on past use of any core for which further funding is not being requested as well as a brief explanation of the reasons for deleting cores, combining facilities, or creating new cores.

When cores use human subjects or animals, include the information required by the 398 form.

**Pilot and Feasibility Studies Program (Renewal applications)—6 pages discussion of P&F program + 12 pages for up to four currently funded or approved P/F project being presented** (3 pages for EACH project)

Provide an overall budget with justifications for proposed future years. The annual budget for the P/F program should be listed in the "other expenses" category in the budget for the Administrative Core.

Include an historical overview of the P/F program since the inception of the P30 Center (NORC, CNRU, or ONRC). For only the most recent 10 years, provide a summary of the P/F recipients (a) who have had publications as a result of the projects, (b) who have received peer-reviewed funding as a result of the studies, and (c) who are still active in the areas of nutritional sciences or obesity-related research. To aid in the review process, use the format shown in Sample Exhibit VII to present P & F program outcomes. Identify any lasting collaborations that resulted from each P/F project and describe any new skills acquired by the P/F recipient or other significant outcomes, such as receipt of an R01 grant. The relationship of each P/F project to one of the research themes of the NORC should be emphasized.

Include a statement that outlines how the NORC has benefited from the P/F grant program, e.g., increased the research base, spawned a new area of research, or enabled an investigator to explore collaborative possibilities.

Describe the current management of the P/F program, including its integration with, and its relationship to, the rest of the administrative structure. Describe plans for future years of the P/F program, including how applications will be solicited, reviewed, awarded, and, if required, terminated. Do not include this information in the write-up of the Administrative Core. If the NORC is composed of a consortium, describe how the P & F program balances support of investigators across the entire consortium.

Include reports (not just tabulated information) on all P/F projects completed during the **current five year project period**. These reports should be brief (no more than one page narrative) and should provide: (a) the name of the investigator, degree(s), professional career status at the time of the award, and current professional career status (if known); (b) an overview of the project, including its significance and salient results; (c) a list of publications resulting from the project; (d) the current status of the investigator's funding, and whether in the same or a related area; and (e) any other significant and pertinent information (such as amount and time period of support, future plans of investigator). Include currently funded, ongoing projects in abbreviated form.

Describe up to four (4) currently funded or approved for funding P/F projects that best represent the P/F work of the Center. Do not describe all currently proposed P/F projects. The applications should be the

best ones received and must have been reviewed in the manner used for all P/F applications. Each of the four P/F project descriptions should be no longer than 3 pages of narrative text and should include:

- a) a budget with justifications for: (1) initial budget period, and (2) entire proposed project
- b) justification for eligibility of the P/F project (how it fits with the NORC's goals)
- c) justification for eligibility of the P/F investigator (see Part I-G)
- d) justification for core use
- e) description of the project.

Due to the timing of the RFA, some or all of the P/F projects may be those that are currently funded. If at all possible, however, the P/F projects should be new ones. It is important for the IRG to be able to evaluate the Center's review "process" by the merit of the P/F projects selected for funding. In either case, provide a list of currently funded P/F projects. It is also important to include the number of applications received during the most recent five-year funding period.

Clearly indicate the **Named New Investigator**, if such a position is being requested, and how he/she was selected. Include salary support for this position in the Administrative Core personnel section. If using Sample Exhibit VII, use an asterisk to indicate previous **Named New Investigators**.

#### **D. SPECIFIC INSTRUCTIONS - Appendix (PHS 398)**

##### **(New Applications)**

Include no more than 12 pertinent publications as an appendix. These should highlight major scientific accomplishments resulting from the most significant research being conducted by proposed Center investigators within the research base. Follow the 398 instructions for the format for submitting appendix materials.

##### **(Renewal)**

Include the narrative portion of the non-competing Annual Progress Report from the last budget period. Depending upon the RFA receipt date, this will most likely be from the project period just prior to the one in which the renewal application is being submitted. As with new applications, include no more than 12 reprints, if desired, highlighting the most significant research being conducted within the research base, as well as the collaborative nature of the research. Follow the 398 instructions for the format for submitting appendix materials.

#### **E. SPECIFIC INSTRUCTIONS-BUDGET CATEGORIES (both New and Renewal)**

Allowable costs and policies governing the research grant programs of the NIH will prevail for NORC applications.

##### **Personnel**

This category should include support for salaries of key personnel within the NORC who contribute to the allowable activities of the Center. Salary support for a full time administrator for the Center is encouraged. Salaries of professional personnel engaged in research activities supported by P/F funds are an allowable budgetary item, as are salaries of professional and technical personnel in core facilities. The salary amount charged to the NORC grant must be commensurate with the time spent on NORC activities. Salary support derived from the grant will depend on the effort provided and on institutional

salary policies; however, current NIDDK practice limits annual increases to 3 percent not to exceed the direct salary cap.

The Center Director is expected to devote an appropriate proportion of his/her time to the NORC (**no less than 20 percent effort**). The application should not include salaries for individual principal investigators on separate research or training grants unless these investigators provide an essential function for NORC activities (e.g., Core Director). No overlap of time or effort between a NORC activity and separately funded research projects is permitted.

Potentially overlapping support between NORC and individual projects, including research project grants (R01), program project grants (P01), Resource-Related Research Projects (R24), Career Development Awards (K-awards), Small Business Technology Transfer awards (R41, R42), and contracts, will be administratively reviewed by the NIDDK and, if appropriate, adjusted to eliminate duplication of funding.

**Stipends for research trainees are not available through the NORC.** Such funding must be sought through other grant mechanisms.

### **Equipment**

If pieces of specialized equipment costing more than \$5,000 are requested (renewal applications only), the application must identify similar equipment already available within the institution and provide a clear justification for purchase in terms of core service being provided to NORC investigators. Requests for general-purpose equipment should be included only after ascertaining the availability of such items within the institution. Justify the request based on this availability. This includes all equipment in future budget years as well as the initial budget period.

### **Supplies**

Consumable supplies directly related to the operational aspects of the NORC core facilities are an allowable expense. This includes office materials as well as laboratory supplies. The supply budgets of separately funded individual research projects must be appropriately reduced to reflect such support, thus eliminating duplication.

### **Research Patient Care Costs**

Research patient care costs (both in-patient and out-patient) are an allowable expense. Attempts should be made to utilize existing clinical facilities, such as those in **Clinical and Translational Science Awards** (CTSA) and individually supported beds. If the CTSA is to be used, include a letter of agreement from either the CTSA program director at the National Center for Research Resources, NIH, or from the Principal Investigator of the CTSA.

Request costs relating to the clinical research efforts of NORC investigators **ONLY** if there is no overlap with other funding. Costs already budgeted in individual projects should be appropriately reduced if such costs are to be transferred to the NORC clinical component. The NORC is not intended to be a facility for health care delivery. Thus, only those patient costs directly related to research activities may be charged to the Center.

### **Consultants**

Include costs associated with consultants (consultant fees, per diem, and travel) when their services are required by the NORC, such as the members of the External Advisory Board.

### **Travel**

Include travel costs for the NORC Director, center administrator, and others as appropriate (i.e., co-Director, core Directors) to attend the annual NORC Director's meeting in the budget of the Administrative Core.

### **Total Requested Amount**

Total direct costs requested should not exceed \$750,000 per year. Not included in these direct cost limits are requests for equipment in the first year of renewal applications.

### **Other**

Unsolicited budget supplements to a NORC grant are not routinely accepted. If a NORC Director determines that a supplement to a NORC grant is necessary, consultation with, and approval of, the NIDDK NORC program director is required prior to the submission of a formal request through the institution's budget office.

## **PART III**

# **REVIEW AND ASSESSMENT**

## **A. REVIEW CONSIDERATIONS**

Upon receipt, the Center for Scientific Review (CSR) staff will screen applications to make sure they adhere to 398 submission guidelines. Rejected applications will be returned to the applicant without review. NIDDK program staff will screen applications for responsiveness to the program requirements and criteria stated in the RFA. If the application is not responsive to the RFA, NIDDK staff will contact the applicant.

Those applications that are complete and responsive will be evaluated in accordance with the criteria stated below for scientific/technical merit by an appropriate peer review group convened by the NIDDK. The written application must be complete because site visits are not possible.

Following the initial review of both new and renewal applications, all scored applications will undergo a second level review by the National Diabetes and Digestive and Kidney Diseases Advisory Council. Applications recommended for approval by the Advisory Council will be considered for funding on the basis of (1) overall scientific and technical merit as determined by peer review, (2) program needs and balance, and (3) availability of funds.

### **Review Criteria**

The mission of the NIH is to support science in pursuit of knowledge about the biology and behavior of living systems and to apply that knowledge to extend healthy life and reduce the burdens of illness and disability. As part of this mission, applications submitted to the NIH for grants or cooperative agreements to support biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

#### **Overall Impact - Overall**

Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the NORC to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the NORC proposed).

#### **Scored Review Criteria - Overall**

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a NORC that by its nature is not innovative may be essential to advance a field.

#### **Significance**

Does the NORC address an important problem or a critical barrier to progress in the field? If the aims of the NORC are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field? What are the strengths of the center's research base (its breadth and depth) and the relevance and interrelation of the separately funded research projects to the focus/theme(s) of the center? Is there a strong scientifically excellent research base in nutrition/obesity and/or other related conditions/diseases at the Center,

which would benefit by the services/programs supported through the NORC? What is the likelihood that the NORC will increase efficiency; promote new research directions and meaningful collaborations among center investigators; facilitate interactions and collaborations among the investigators; and prove cost-effective? In renewal applications, have the benefits of the center been documented in the forms of increased collaboration, new research directions, and cost savings? What are the strengths of the clinical research components of the center?

### **Investigator(s)**

Are the PD/PIs, collaborators, and other researchers well suited to the NORC? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project? Are the center investigators responsible for the individual research projects willing to interact with each other and contribute to the overall objectives of the NORC? What are the scientific and administrative leadership abilities of the proposed center Director and Associate Director(s) and their commitment and ability to devote adequate time to the effective management of the program? If requested, does the Named New Investigator appear well qualified and eligible for support?

### **Innovation**

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed? Are the Pilot & Feasibility (P&F) studies submitted for evaluation from applicants eligible for P&F funding? Does the selection process by which the individual P&F studies were selected appear appropriate? Does the center encourage 'high-risk', innovative ideas through their P&F program? For renewal applications, are data provided to document the outcome of all P&F projects completed in the last five years, including those that failed to lead to further funding? Have the cores provided new methods, techniques, and/or resources and developed ways to support investigators in new areas of nutritional sciences and/or obesity research, as appropriate to the purpose of the core and the research supported by the Center?

### **Approach**

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the NORC? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the NORC involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the

inclusion of children, justified in terms of the scientific goals and research strategy proposed?

How appropriate and relevant are the proposed cores and the modes of operation (such as potential utilization, prioritization of requests for services, cost-recovery, and quality control monitoring)? Will at least two federally-funded research investigators use each core and how significant with their use be? Will the cores provide opportunities not otherwise available to the investigators through other available federally funded and/or institutional resources; represent appropriate cost savings/cost sharing advantage; and stimulate the development of new approaches? Is appropriate administrative organization proposed for the following:(a) coordination of ongoing research between the separately funded projects and the center, including mechanisms for internal monitoring;(b) establishment and maintenance of internal communication and cooperation among the center investigators;(c) mechanism for selecting and replacing professional or technical personnel within the cores;(d) mechanism for reviewing the use of, and administering funds for, the P&F program;(e) management capabilities, including fiscal administration, procurement, property and personnel management, planning, budgeting, and other appropriate capabilities? Is there efficient and effective use and/or planned use of the limited enrichment funds, including the contribution of these activities to the stated goals of the center?

### **Environment**

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Is there evidence of institutional commitment to the program, including lines of accountability, regarding management of the center grant and the institution's contribution to the management capabilities of the center? Is there clear potential for interaction with scientists from other departments and institutions?

***Protections for Human Subjects*** For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the [Human Subjects Protection and Inclusion Guidelines](#).

***Inclusion of Women, Minorities, and Children*** When the proposed Center involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the [Human Subjects Protection and Inclusion Guidelines](#).

**Vertebrate Animals** The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the [Worksheet for Review of the Vertebrate Animal Section](#).

**Biohazards** Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

**Resubmissions** For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

### **Renewals**

For Renewals, the committee will consider the progress made in the last funding period, as follows:

#### Research Base:

- Does the Center show evidence of a stable or growing research base with strong and consistent record of scientific excellence and achievement reflected in an outstanding level productivity and continuing success in securing peer-reviewed research funding?
- Does the Center show evidence of fostering multi-disciplinary collaborations among Center investigators?

#### Biomedical Cores:

- Is there a significant list of publications arising from each core that are relevant to nutrition/obesity and related conditions in renewal applications?
- Is there a significant fraction of papers that a) acknowledge the Center and b) do not have core personnel as co-authors?
- Are the number and listing of Center investigators who have used the core and resultant key advances consistent with the level of core investment?
- Do the number and listing of investigators who have used the core multiple times indicate satisfaction and continuing need for core services?
- Are there sufficient numbers of users who are not core directors/personnel or their collaborators?
- Are the use, utility, quality control, and cost-effectiveness of each core appropriate and adequately described?
- Are the numbers of services/tests offered by each core indicative of a growing need and sufficient to justify continued support, and if not, has the Center provided evidence of ability to evolve cores to meet changing needs of the research community?
- If a research core has been discontinued during a prior funding period, is there a description/justification of the process for discontinuing the referenced research core?

- Is the capacity of each core with current resources sufficient to serve the needs of the Center community?
- Does the Center provide evidence of Program Income and sufficient institutional support?

Administrative Core:

- Has the administrative structure proven effective?
- Has the enrichment program been effective?
- Are the Director(s) appropriately qualified to lead the NORC?

Pilot & Feasibility Program:

- Are the numbers and types of P&F awards well justified?
- Are papers generated under these awards, projects successfully funded with independent grants, and key advances linked to these awards well documented and consistent with the level of support provided?

Clinical Component:

Does the NORC provide meaningful support for patient-oriented research in a manner that fosters clinical/translational research? Are the services appropriate for the NORC Center members/research base?

### **Additional Review Considerations - Overall**

As applicable for the NORC proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact/priority score.

The following additional review criteria apply to all new and renewal NORC applications: Foremost, does the research base to be supported by the Center show evidence of a strong and consistent record of productivity and peer-reviewed funding in Center-related research areas? Are the research base and biomedical research cores consistent with the focus/themes of the NORC? Is the requested budget directly correlated to the breadth, quality and relevance to nutrition and/or obesity and related areas of the research base being served by the Center? Do the proposed cores fill a need present in the nutrition and obesity research community, and will they provide services that would otherwise be unavailable, or be more cost-effective to conduct centrally? Is the necessary technical and analytical expertise available? Does the application demonstrate ability to monitor use and utility of the cores, and provide approaches to ensure continuing development and evolution of services as needs of the community change? Do the existing Centers show clear evidence of successful implementation of a recharge structure to support expanded and/or evolving Center activities? Do the new proposals document a clear intent to implement a recharge structure to support expanded and/or evolving Center activities?

### **Select Agent Research**

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate bio-safety, bio-containment, and security of the Select Agent(s).

### **Resource Sharing Plans**

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) [Data Sharing Plan](#); 2) [Sharing Model](#)

[Organisms](#); and 3) [Genome Wide Association Studies \(GWAS\)](#).

### **Budget and Period of Support**

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

### **SCORED SECTIONS OF APPLICATION:**

For these P30 Center applications, reviewers will be asked to evaluate the following individual sections, and the Scientific Review Officer will record these scores:

- Research base, including the focus, quality of research, collaborations among members, relevance to the NORC's stated research focus, and, for renewal applications, the growth or evolution of the research base.
- Each scientific core, as regards need for proposed services; number of users; qualifications of personnel; management, including prioritization and responsiveness to the needs of the users; quality control management; and any appropriate developmental work
- The administrative core, including committee structure, center membership criteria, and lines of communication. The clinical component; enrichment program; and Named New Investigator, if requested, will also enter into this evaluation.
- Pilot and Feasibility program, including the quality and appropriateness of the four submitted P/F applications as well as the organization of the P/F overall process of solicitation, review, and monitoring of projects.
- Center Director (PI) as regards leadership and commitment to the stated goals of the NORC.

The overall impact score is not the average of the scores for all these components.

## **C. ASSESSMENT AND REPORTING REQUIREMENTS- PROGRESS REPORTS**

### **Background**

The NORC program as a whole, and each center individually, is evaluated on an ongoing basis by NIDDK staff. The activities and accomplishments of each NORC are documented using several approaches. The annual progress report serves to highlight each NORC's accomplishments, including productivity of individual investigators; significance of the research conducted by center investigators; enhanced communication and collaboration facilitated by the NORC; use of P/F funds; and overall Center impact on the institution and the Center members.

In addition, NIDDK staff members must periodically prepare reports for the NIDDK Director and the NIDDK National Advisory Council. These reports may pertain to the productivity of the Centers, overlap of resources (including the research base and cores), cost-effectiveness, and contribution to the advancement of the field(s). These reports may be based on progress reports from the NORCs, grant applications, and on information solicited prior to the yearly Center Directors' meeting. If necessary, NIDDK staff or consultants may visit individual centers to aid in these evaluation activities. The Annual Center Directors' meeting, usually held at one of the NORCs, provides an opportunity for evaluation of the host center's program and discussion of future NORC goals and projects.

### **General Plan for Interim Assessment**

To assist in interim assessments of the NORC, the following are helpful to the NIDDK staff:

- a) Center Directors' meeting(s) – these meeting(s), attended by NIDDK staff and senior management, are mandatory for all Center Directors or, if need be, the co-Director. Center administrators are strongly encouraged to attend.
- b) Minutes of NORC meetings-copies of the minutes of Internal Executive Committee meetings and the External Advisory Board meetings;
- c) Newsletters-current newsletters from the NORC and from the parent institution, if these mention or highlight the NORC.
- d) In-House Assessments-The Director of a NORC should use Center's External Advisory Board meetings to assess the activities and programs of the NORC. The minutes from the Advisory Board meetings may be included as part of the annual progress report OR may be sent in as they become available.
- e) Annual Progress Report-The annual Grant Progress Report, which is due two months before the anniversary date of the award, must be submitted as described in the PHS Form 2590 application instructions. Since the NORCs are large, multifaceted grants, a uniform reporting format for the annual progress report is desirable.

The format suggested for the narrative portion of the report follows below in Section C. Information such as External Advisory Board meeting minutes, newsletters, and other pertinent items already sent to the NIDDK program director need not be included.

## **D. FORMAT FOR ANNUAL PROGRESS REPORTS**

Use this outline in conjunction with the narrative portion of the Grant Progress Report (PHS Form 2590) to provide information about the NORC. <http://grants.nih.gov/grants/funding/2590/2590.htm>

**All information should begin from the time of the last Progress Report. Include a Table of Contents.**

Please provide information relevant to NORC activities, membership, and publications over the past year only. Note that PMCID #s are required elements.

### **I. FORM PAGES**

- Face page
- Cumulative Budget for Center (PHS 2590 Form Page 2)
- Budget and Justification for each Core (PHS 2590 Form Page 2 for each Core)
- List of **NEW key personnel only** followed by their biosketches
- **Other support for all key personnel ONLY** (i.e. only for personnel listed as “KEY” in the Notice of Grant Award, or their recent replacements); please verify that “other support” information is current and that effort does not exceed 12 calendar months for any individual.

### **II. RESEARCH BASE (1-2 pages MAX for narrative text + Tables A, B and Section C below)**

(Table) A. List Current Center Investigators – **list only changes** in membership since last year’s report

- New members (name, dept, area of interest)
- Members lost (due to transfer, inactivity or other)

(Table) B. Enumeration & list of

- Publications citing center support during the past year (**include PMCID #**)
- Publications directly traceable to center activities during the past year (**include PMCID #**) with an explanation of why the center was not cited.
- Major changes in research grant support (new and/or ending from prior year)

(Text) C. New collaborative activities

- List & briefly describe any intra-center joint programs or projects
- List & briefly describe any inter-center joint programs or projects
- List collaborative publications (include PMCID#)

### **III. ADMINISTRATIVE + ENRICHMENT COREs (1-2 pages MAX for narrative text)**

(Text or Table) A. Activities raising awareness and interest in nutrition and/or obesity research, locally, regionally, and nationally:

- NORC-sponsored seminars & symposia (only those sponsored by or supported with NORC funds)
- Regional and national presentations (list all that were sponsored by or supported with NORC funds; i.e. presentations of research that was supported by NORC funds)
- Collaborations with other NORCs, institutions and centers

(Text or Table) B. Activities enhancing nutrition and/or obesity education and training opportunities for patients, students, scientists and clinicians. NORC-sponsored training activities (training, symposia, etc.) should be listed in IIIA, if desired)

#### **IV. CLINICAL COMPONENT (If applicable; 1-2 pages MAX for narrative text)**

(Text) A. Overview of services provided over the past year  
B. Accomplishments & collaborations that have developed over the past year

#### **V. BIOMEDICAL RESEARCH CORE REPORTS (1-2 pages MAX for narrative text per core)**

*For each core:*

(Table or Text) A. Significant changes from previous year

- New personnel
- New services or changes in existing services

(Table or Text) B. Usage metrics (tabulated)

- Number of users - broken down by members vs. non-members, including the distribution of core activity for each
- Number of publications citing center support that used the core

(Text) C. Significant accomplishments, such as:

- R&D to improve core services
- Surveys to evaluate core services

#### **V. PILOT & FEASIBILITY PROGRAM (1-3 pages MAX for any narrative text)**

(Table) A. Solicitation

- Number of new (or continuing) P&F applications reviewed (may also include number of letters of intent received, if applicable)
- Types of applications reviewed
  - new invest, established investigators new to field, innovative partnership
  - basic, clinical, translation, community/environmental interventions
  - inter or trans-disciplinary
- Review process (if altered from previous years)

(Table or Text) B. New Awards

- Number of new (or continuing) P&F awards
- Types of awards
  - new invest, established investigators new to field, innovative partnership
  - basic, clinical, translation, community/environmental interventions
  - inter or trans-disciplinary
  - joint funding (i.e., with other Centers, programs, or NORCs)
- Titles, PIs, brief description (2-3 sentences)

(Table or Text) C. Awards funded previous year(s)

- Titles, PIs, brief description (repeated from prior year report)
- Progress – brief description (short paragraph)
- Presentations, manuscripts, publications (include PMCID#)
- Grant applications submitted and new funding, if applicable (Include mechanism, R21, K, R01, etc.)

## **VI. MAJOR RESEARCH ACCOMPLISHMENTS (3-6 pages MAX for narrative text)**

A. Describe **significant findings** and provide PMCID# for supporting center citations that typify activity at your center and that highlight recent research accomplishments.

B. Describe progress along a translational continuum in your center for a selected topic area/project. This can be a retrospective analysis, or an example of a current project or area that is actively progressing.

## **VII. PROGRESS MADE WITH ANY SUPPLEMENTAL FUNDS (REQUIRED)**

If your NORC received supplemental funds in the past 1-2 years, please be sure to include an update on progress made with these funds. Examples include:

- ARRA or NIDDK funds for equipment (list equipment purchased, if not reported previously) or other services
- ARRA or NIDDK funds for P&F projects (designate the P&F projects supported with ARRA vs. NIDDK funds, and research progress on each)

## **VIII. CHECKLIST, HUMAN SUBJECTS, VERTEBRATE ANIMALS, & OTHER REQUIRED FORM PAGES**

Specific Examples:

- Inclusion Enrollment Report Format Page (submit this form page for each P&F awardee using human research subjects during the past 1-2 years)
- Targeted/Planned Enrollment Format Page (submit this form page for each new P&F awardee who plans to study human research subjects, but whose study is just beginning and enrollment hasn't started yet)
- IRB and/or IACUC approval information for all P&F studies involving human research subjects and/or vertebrate animals (a listing, with approval dates, PI names, project title, etc., is acceptable)
- All Personnel Report"
- External Advisory Report: If you have not already submitted a report from your External Advisory meeting during the past year, please include a copy in your annual progress report.

**NOTE: An abbreviated version of the progress report may be submitted for the year of support in which the renewal application is being submitted.** While the Grant Progress Report may be attenuated, it MUST contain the following elements:

- face page signed by the appropriate University officials;
- budget pages, with justifications;

- list of cores and names of core directors;
- list of faculty, departmental affiliations, and research interests [can be one sentence];
- titles, Principal Investigator's name, and dates for P/F studies for the last budget period and for those projects that are continuing or are planned for support;
- a brief [2-5 page] summary of Center core activities, including any changes in services offered;
- at least a one page report on the most significant scientific advances from the Center in the past year, along with the appropriate publication citation, in layman's terms;
- all the usual assurances;
- any personnel changes; and
- checklist.

*These guidelines update the policies covering NORC grants; earlier versions should be discarded. Some redundancy exists within the guidelines to emphasize key issues related to a NORC. If questions remain after reading these guidelines, contact the individuals listed below.*

Direct inquiries regarding programmatic issues and requests for the Administrative Guidelines to:

Mary E. Evans, Ph.D.  
 Director, Nutrition Obesity Research Centers Program  
 Division of Digestive Diseases and Nutrition  
 National Institute of Diabetes and Digestive and Kidney Diseases  
 Two Democracy Plaza, Room 681  
 6707 Democracy Blvd., MSC 5450  
 BETHESDA M.D. 20892-5450  
 Telephone: (301) 594-4578  
 Email: [evansmary@niddk.nih.gov](mailto:evansmary@niddk.nih.gov)

Direct inquiries regarding fiscal matters to:

Sharon Bourque  
 Grants Management Specialist  
 Division of Extramural Activities  
 National Institute of Diabetes and Digestive and Kidney Diseases  
 6707 Democracy Blvd. Room 719  
 BETHESDA MD 20892-5450  
 Telephone: (301) 594-8846  
 E-mail: [bourques@extra.niddk.nih.gov](mailto:bourques@extra.niddk.nih.gov)

This document affects all new and renewal applications effective May 2011.

**SAMPLE EXHIBITS**

- I. Consolidated Budget for 1st year of Requested Support**
- II. Distribution of Professional Effort on This Application**
- III. Summary of Total Current and Pending Support of all Center Participants**
- IV. Collaboration Between Center Participants**
- V. Publications Citing/Supported by the NORC (For Renewal Applications Only)**
- VI. Use of Core Facilities**
- VII. Pilot Project Outcome Table (For Renewal Applications Only)**

**SAMPLE EXHIBIT I**

**CONSOLIDATED BUDGET FOR 1<sup>st</sup> YEAR OF REQUESTED SUPPORT**

<b>Budget Category</b>	<b>Core A</b>	<b>Core B</b>	<b>Core C</b>	<b>Core D</b>	<b>Core E</b>	<b>P/F Projects</b>	<b>TOTALS</b>
<b>Personnel</b>							
<b>Consultant Costs</b>							
<b>Equipment</b>							
<b>Supplies</b>							
<b>Domestic Travel</b>							
<b>Foreign Travel</b>							
<b>Patient Care Costs</b>							
<b>Alterations/ Renovations</b>							
<b>Other Expenses</b>							
<b>Contractual Costs</b>							
<b>TOTALS</b>							

**SAMPLE EXHIBIT II**

**DISTRIBUTION OF PROFESSIONAL EFFORT (person-months) ON THIS APPLICATION**

*\*Star the calendar month effort (See Core A) when that individual is the Core Director*

<i>Participating Investigators*</i>	<i>Core A</i>	<i>Core B</i>	<i>Core C</i>	<i>Core D</i>	<i>P/F (Project #)</i>	<i>Application Total</i>	<i>Other Support</i>
<i>Dr. A</i>	<i>* 3.0</i>				<i>3.0 (3)</i>	<i>6.0</i>	<i>6.0</i>
<i>Dr. B</i>		<i>0.6</i>		<i>0.6</i>		<i>1.2</i>	<i>4.8</i>
<i>Dr. C</i>	<i>0.6</i>				<i>1.2 (4)</i>	<i>1.8</i>	<i>8.4</i>
<i>Dr. D</i>			<i>1.2</i>	<i>*1.2</i>		<i>2.4</i>	<i>6.6</i>
<i>Etc.</i>							

### **SAMPLE EXHIBIT III**

#### SUMMARY OF TOTAL CURRENT AND PENDING SUPPORT OF ALL CENTER PARTICIPANTS

#### **SAMPLE EXHIBIT III-A: CURRENT NUTRITION AND/OR OBESITY-RELATED RESEARCH BASE SUPPORT**

Grants to be included: R01s, R21s, R37s, R24s, K-series, U01s (only if they specifically use NORC cores/services), P01s (if the total funds are already listed for the Principal Investigator of the P01 funds, support for the sub-project should be shown in parentheses), and peer-reviewed grants funded through other Federal Agencies or non-federal groups. Do not include this NORC in the research base. Include **ONLY** nutrition/obesity and related research support (i.e., not diabetes-specific, digestive diseases, or other non-nutrition/obesity research); Indicate whether an investigator has other, non-nutrition/obesity funding in Exhibit III-C.

Some institutions may have multiple NIDDK-funded centers. In those cases, grants that utilize multiple centers should be high-lighted and the other NIDDK Center(s) utilized should be specified. **(Annual direct costs for grants whose research aims fall into more than one distinct NIDDK Center should be divided/reduced proportionately, e.g. 50% NORC and 50% Diabetes Research Center).** List grants with support related to nutrition/obesity first (Exhibit III-A), followed by pending nutrition/obesity-related support (Exhibit III-B), and then non-nutrition/obesity- related research support (Exhibit III-C) and other 'pending' research support (Exhibit III-D). **Grants/projects whose research funding is in a no-cost extension and/or will terminate before the NORC funding period will begin should be included in a separate list.** List training grants (T32) and fellowships (F32) related to nutrition and/or obesity **LAST** in the table below (III-A). Do not include T32/F32 direct costs in the total funding for the research base.

*Principal Investigator/ [Co-Investigator]	Supporting Organization/ Grant Number	Title	Project Period	Other NIDDK Center(s) used**	Annual Direct Costs	Direct Costs Relevant to the NORC***
<b>Doe, John [Stellar, Fred]</b>	<b>NIH P01 DK12345</b>	<b>Mechanisms of Vitamin E Action</b>	<b>4/1/2009 – 3/31/2014</b>	<b>DDRC</b>	<b>\$500,000</b>	<b>\$250,000</b>
<b>Jones, James</b>	<b>NIH R01 AG65432</b>	<b>Vitamin K and Bone Density</b>	<b>7/1/2008 – 6/30/2013</b>	<b>DRC, DDRC</b>	<b>\$300,000</b>	<b>\$100,000</b>
Smith, Edith	DOD	Obesity and its Health Effects	7/1/2010 – 6/30/2015		\$180,000	\$180,000
Miles, Amelia	CDC	Frequency of Childhood Obesity	5/1/2011 – 4/30/2016		\$350,000	\$350,000
Etc.						

\* For Multiple PI grants, list the grant under the name of the Contact PD/PI with relevant other PIs (optional) listed in [ ]. Do not list any grant more than once.

\*\* List and **high-light in BOLD** grants that utilize other NIDDK Center(s). Specify the other Center(s) used. Define any abbreviations. (For example: DRC= Diabetes Research Center; DDRC= Digestive Disease Research Center, etc.)

\*\*\* Divide/reduce the amount of direct costs proportionately according to number of NIDDK Centers used. Only provide direct costs that are relevant to the NORC. To calculate total grant funding for the NORC, sum this column (excluding T32 and F32 support) and calculate the funding from NIDDK and the % from government funding.

**EXHIBIT III-B: PENDING NUTRITION AND/OR OBESITY-RELATED RESEARCH BASE SUPPORT**

Include the same type of grants as listed above in SAMPLE EXHIBIT III-A. Use the same column headings except the last one.

------(AS ABOVE)-----

**EXHIBIT III-C: CURRENT SUPPORT OTHER THAN NUTRITION AND/OR OBESITY-RELATED**

For those members indicated by an 'X' in EXHIBIT III-A.

------(AS ABOVE)-----

**EXHIBIT III-D: PENDING SUPPORT OTHER THAN NUTRITION AND/OR OBESITY-RELATED**

For those members indicated by an 'X' in EXHIBIT III-A

------(AS ABOVE)-----

# EXHIBIT IV

## COLLABORATIONS BETWEEN CENTER PARTICIPANTS

	J O N E S	S M I T H	A D A M S	P A R K	E V E R S	K N I G H T	O L S O N	S U N	T A Y L O R	Y U	Z A N E
JONES	X	*		*	*		*		*		*
SMITH	*	X			*		*				*
ADAMS			X	*			*	*	*		
PARK	*		*	X		*					
EVERS	*	*			X			*			
KNIGHT				*		X				*	
OLSON		*		*			X				*
SANDS			*		*			X		*	
TAYLOR	*		*						X		
YOUNG						*		*		X	
ZANE	*	*					*				X

\*Indicates collaboration as evidence by joint publications, abstracts, or research grants or by joint research projects.

## **EXHIBIT V--FOR RENEWAL APPLICATIONS ONLY**

### PUBLICATIONS CITING/SUPPORTED BY THE NORC

<u>Core or P&amp;F/P.I. Name)</u>	<u>Publications</u>	<u>Primary</u>	<u>Secondary</u>
Core A/Brown	Brown, A.C.; Jones R.C.; Smith, A.J. Effect of omega-3 fatty acids on oxidative stress in the human adipocyte. Obesity Research, 2008 volume; page # PMCID#	Core A	
	Brown, A.C.; Cheng, A.G.; Anderson, J.C. Effect of physical activity intensity on weight loss maintenance. Amer. College. Sports Med., 2010, volume: page#, PMCID#.	Core A	Core C
Core B/Cheng	Cheng, A.C.; Meyer, G.C. Linkage studies in animal models of obesity. Nature Genetics, 2011, volume: page#, PMCID#.	Core B	Core A
	*Smith, F.G.; Cheng, A.C.; Tissue Specific Knockout of Glut4 PNAS, 2009, V: page#, PMCID#.	Core B	
P&F/Smith	Smith, F.L.; Davis, S.E.; Morris, J.L. Dietary Composition and Meal Patterns in Pre- and Post-Gastric Bypass Surgery Patients. Obesity, 2009, volume: page#, PMCID#.	Core C	
P&F/Jones	Jones, T.L.; Hathaway, J.B; Clemmons, A.H.; Effect of Excessive Gestational Weight Gain on Glucose Tolerance in Off-spring. Amer. J. Clin. Nutrition, 2010, volume, page#, PMCID#.	NONE	

Instructions: List each publication only once under the Core (or P&F project/PI name) most significantly contributing to the work. Each publication listed should cite the NORC Center grant number. For any publications that received Center grant support but did not cite the Center grant number, use an asterisk (\*) at the beginning of the publication listing. The research core most significantly contributing to the work should be signified as "Primary." All other contributing research cores are designated as 'Secondary'. Use separate headings for each research core (i.e. publications supported by each 'primary' core should be grouped together), followed by any P&F projects that used no core support at the end of the listing of Center publications.

## EXHIBIT VI-A

### USE OF CORE FACILITIES (FOR NEW APPLICATIONS ONLY)

CORE: NAME Determination/Services Rendered A. B.					
	Users	Funded Projects with Identifying Number	Period of Performance	Cores/Services Used	Estimated Use and Comments
1.					
2.					
3.					

  

EXAMPLE					
Core A: Molecular Biology Determination/Services Rendered A. Isolation of DNA and RNA B. Analysis of gene expression using GeneChips and microarrays C. DNA sequencing D. Proteomics/Metabolomics					
	Users	Funded Projects with Identifying Number	Period of Performance	Cores/Services Used A B C D	Estimated Use and Comments*
1.	J. F. Smith	R01 DK00000-0X	03/07/10-03/06/15	X X	A. 5 per month C. 100 per month
2.	S. R. Jones	K08 DK00000-0X	01/04/09-01/03/13	X X	B. 40 per week D. 8x per month
3.	R. Brown	R01 GM00000-0X	09/01/08-08/31/12	X	A. 16 per week for 6 months

  

Core B: Eating Behavior Assessment Determination/Services Rendered Same format					
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\*Indicate anticipated use for each member/grant as number of times per designated time period. The designated time period may be per month, per week, per year, or a combination, as appropriate.

**EXHIBIT VI-B (FOR RENEWAL APPLICATIONS ONLY)**

**USE OF CORE FACILITIES**

CORE: NAME Determination/Services Rendered A. B.					
	Users	Funded Projects with Identifying Number	Period of Performance	Cores/Services Used	Actual Use and Comments
1.					
2.					
3.					

  

<b>EXAMPLE</b>					
Core A: Molecular Biology Determination/Services Rendered A. Isolation of DNA and RNA B. Analysis of gene expression using GeneChips and microarrays C. DNA sequencing D. Proteomics/Metabolomics					
	Users	Funded Projects with Identifying Number	Period of Performance	Cores/Services Used A B C D	Actual Use and Comments*
1.	J. Smith	R01 DK00000-00	03/07/10-03/06/15	X X	A. 5 per month C. 100 per month
2.	S. Jones	K08 DK00000-00	01/04/09-01/03/13	X X	B. 40 per week D. 8 per month
3.	R. Brown	R01 GM00000-00	09/01/08-08/31/12	X	A. 16 per week for 6 months

  

Core B: Eating Behavior Assessment Determination/Services Rendered Same format					
--	--	--	--	--	--

\*Indicate anticipated use for each member/grant as number of times per designated time period. The designated time period may be per month, per week, per year, or a combination, as appropriate.

## **EXHIBIT VII**

### **PILOT & FEASIBILITY (P&F) PROJECT OUTCOMES- FOR RENEWAL APPLICATIONS ONLY**

Set up column headings:

P&F Project Number

Investigator (last name, first name)

Department

P&F Funding Dates (MM/YY to MM/YY)

Amount of P&F (direct costs for entire P&F project period)

P&F Project Title

Type of P&F Investigator (New, Established, or New to Nutrition/Obesity)

Type of P&F Research (Basic, Clinical, Translational)

Publications (# of papers, # of abstracts)

Subsequent Grant Applications Funded (Yes, No, Pending)

Subsequent Grant Number (of the grant received most proximate in time to the P&F award, i.e. for investigators who received funding 5-10 years ago, this will usually not be current funding)

Subsequent Grant Project Period (MM/YY to MM/YY)

Amount of Subsequent Grant Award (Total Direct Costs for Duration of Award)

Still in Nutrition/Obesity Research (Yes, No)